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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,947	02/11/2004	Barry M. Freifeld	IB-1842	5349

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EXAMINER	
KIKNADZE, IRAKLI	

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,947	FREIFELD ET AL.	
	Examiner	Art Unit	
	Irakli Kiknadze	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-7 and 17-28* is/are allowed.

6)☒ Claim(s) *8-27 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: It has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It doesn't constitute a limitation in any patentable since. Examiner recommends substituting, in line 3, "an X-ray source capable of emitting an X-ray beam "with -- an X-ray source emitting an X-ray beam --. Appropriate correction is required.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 8-16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd (US Patent 4,977,585).

With respect to claims 8-11, 13 and 29, Boyd teaches (Fig.2) an imaging device comprising: an x-ray source (17); an X-ray detector (18); and a means for shielding (28) an object to be irradiated by the x-ray source (17) so as to form an image detected by the detector (18); wherein the means for shielding limits external exposure of x-ray radiation produced by the x-ray source (17) (column 2, lines 32-44 and 51 through column 3, line 10). Boyd fails to teach that the means for shielding limits external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device; and wherein the means for shielding has a mass of less than 200 kg or less than 14 kg or less than 10 kg. All X-ray imaging systems produce unintended radiation emissions to operators in proximity to the systems through scatter, transition, and leakage. Various regulatory agencies have determined the energy levels and time durations to which an operator is exposed. In the United States of America, 21 CFR § 1020.40 (c)(1)(i) provides a regulatory standard specifying that: "radiation emitted from the cabinet x-ray system shell not exceed an exposure of 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface". It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sufficient shielding means for shielding external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device of Boyd to meet federal radiation safety

requirement allowing to provide the safe working environment protecting the operators from unnecessary x-ray exposure. Further, It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the less shielding material save for sufficient shielding in the ranges of: less than 200 kg or less than 14 kg or less than 10 kg, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in art. As a result, less shielding provides more mobile, portable and compact imaging device.

With respect to claim 12, Boyd teaches that the means for shielding (31) is disposed between the x-ray source and the detector (18) (Fig.4; column 3, lines 1-9).

With respect to claims 14-16, Boyd teaches claimed invention except that the X-ray has an energy selected from the group comprising: 10-130 kV, 20-130 kV, and 70-80 kV or has a wavelength between about 10^{-5} to 10^{3} Å or a wavelength between about $(10^{-5} - 10^{3})$ x10 meters. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the X-ray having an energy selected from the group comprising: 10-130 kV, 20-130 kV, and 70-80 kV or has a wavelength between about 10^{-5} to 10^{3} A or a wavelength between about $(10^{-5} - 10^{3})$ x10 meters it the device of Boyd, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art.

5. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heesch (US Patent 6,325,538 B1).

With respect to claim 29, Heesch teaches an imaging device (10) for imaging a sample (18) contained within a shielded volume comprising (Fig.3):

a) means for generating penetrative photons (36) for imaging a sample (18);

b) means for detecting penetrative photons (35) transmitted through the sample (18) and creating an image; and

c) means for shielding the penetrative photons (50, 47, 52 and 53) (Figs. 4A-4D; column 6, lines 52-67 and column 7, lines 45-54). Heesch fails to teach that the means for shielding limits external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device. All X-ray imaging systems produce unintended radiation emissions to operators in proximity to the systems through scatter, transition, and leakage. Various regulatory agencies have determined the energy levels and time durations to which an operator is exposed. In the United States of America, 21 CFR § 1020.40 (c)(1)(i) provides a regulatory standard specifying that: "radiation emitted from the cabinet x-ray system shell not exceed an exposure of 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface". It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sufficient shielding means for shielding external radiation to a level at or below 0.5 milliroentgen per hour at any point 5 centimeters outside an external surface of the imaging device of Heesch to meet federal radiation safety requirement allowing to provide the safe working environment protecting the operators from unnecessary x-ray exposure.

With respect to claim 30, Heesch teaches means for telescoping the generating means (36) closer and further away from the detecting means (35) (Figs 7 and 8; column 8, lines 33-44).

6. Claims 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heesch (US Patent 6,325,538 B1) as applied to claim 29 above, and further in view of Goldstein (US Patent 6,448,571 B1).

With respect to claim 31, Heesch teaches claimed invention except for means for mechanically protecting personnel from movements of the imaging device. Goldstein teaches means (100) for mechanically protecting personnel (114) from movements of the C-arm x-ray emitter (18) and from scattered x-ray radiation of the imaging device (Fig. 4; column 4, lines 48-63). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use means for mechanically protecting personnel as suggested by Goldstein in the device of Heesch, since such modification would mechanically protecting personnel from movements of the C-arm x-ray emitter and from scattered x-ray radiation of the imaging device while providing the safe working environment for the operators.

7. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heesch (US Patent 6,325,538 B1) as applied to claim 29 above, and further in view of Levine et al. (US Patent 6,389,101 B1).

With respect to claims 32 and 33, Heesch teaches claimed invention except for means for translating and rotating the sample relative to the imaging device and generating three-dimensional representation of the sample. Levine teaches means for translating

and rotating the sample relative to the imaging device and generating three-dimensional representation of the sample (column 6, lines 17-27). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use teachings of translating and rotating the sample relative to the imaging device and generating three-dimensional images as suggested by Levine in the device and method of Heesch, since such modification would allow generating three-dimensional images for enhanced visual interpretation of the sample.

Allowable subject matter

8. With respect to claims 1-7, prior art fails to teach or make obvious an X-ray imaging device for imaging a sample, wherein the sample is within an X-ray shielded volume comprising: a first volume shield defining an elongated generally convex receptacle for receiving a first portion of the sample and having therein a transverse elongated shielding portion slidably coupled to a source beam shield; and a second volume shield defining an elongated generally convex receptacle for receiving a second portion of the sample, and having therein a transverse elongated shielding portion slidably coupled to an exit shield as clamed in combination with all elements of claim 1.

9. With respect to claims 17-28 prior art fails to teach or make obvious an X-ray imaging device for imaging a sample contained within an X-ray shielded volume comprising: an X-ray shielded volume comprising: a core volume shielded by a left

volume shield and a right volume shield separably connected so as to permit insertion and removal of a sample, the core volume having a top opening and a bottom opening, a shielded telescoping sleeve permitting elongation of a beam path volume as claimed in combination with all elements of claims 17 or 28 as applied.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irakli Kiknadze whose telephone number is 571-272-2493. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on 571-272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 19, 2005
Irakli Kiknadze
IK

EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER